

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMES V. CARTMELL, WAYNE R. STURTEVANT
and MICHAEL L. WOLF

Appeal No. 96-0928
Application 08/310,971¹

ON BRIEF

Before McCANDLISH, Senior Administrative Patent Judge, and STAAB
and McQUADE, Administrative Patent Judges.

McCANDLISH, Senior Administrative Patent Judge.

¹ Application for patent filed September 23, 1994. According to appellants, this application is a continuation-in-part of Application 07/862,456, filed April 2, 1992, now U.S. Patent No. 5,429,589, issued July 4, 1995.

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DECISION ON APPEAL

This is a decision on an appeal from the examiner's rejection of claims 1 through 19.² Claim 20, the only other claim pending in the application, has been withdrawn from consideration as being directed to a non-elected invention.

The subject matter here claimed relates to a wound dressing having a flexible absorbent layer 12. According to appellants' invention as defined in the presently appealed claims, a partially dehydrated hydrogel in which a portion of the water has been removed is impregnated into the absorbent layer such that the hydrogel can absorb wound exudate upon contact with the wound.

Claim 1 is representative of the claimed subject matter presently on appeal. A copy of this claim, as it appears in the appendix to appellants' brief, is appended to this decision.

² An appeal in appellants' parent application Serial No. 862,456 (see appeal No. 94-1384) resulted in a reversal of the examiner's rejection under 35 U.S.C. § 103 and the introduction of a new ground of rejection pursuant to 37 CFR § 1.196(b). All of the appealed claims in this parent application recited that the dehydrated hydrogel in the absorbent layer of the wound dressing was substantially void of water. This limitation, which no longer appears in the claims now on appeal in the present continuation-in-part application, was the subject of our new ground of rejection under 35 U.S.C. § 112, second paragraph, in the parent application.

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The following references are relied upon by the examiner in support of his rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103:

Robins	2,858,830	Nov. 4, 1958
Perrault et al. (Perrault)	4,717,378	Jan. 5, 1988
Wokalek	5,076,265	Dec. 31, 1991
Cartmell et al. (Cartmell)	5,115,801	May 26, 1992

(filed May 2, 1990)

The grounds of rejection are as follows:

1. Claims 1 through 5, 7 through 14, 16, 17 and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cartmell.

2. Claims 1 through 5, 7 through 14, 16, 17 and 19 additionally stand rejected under 35 U.S.C. § 103 as being unpatentable over Cartmell in view of Perrault.

3. Claim 18 stands rejected under 35 U.S.C. § 103 as being unpatentable over Cartmell in view of Perrault and Robins.

4. Claims 1 through 6 and 10 through 15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wokalek.

5. Claims 1 through 6 and 10 through 15 additionally stand rejected under 35 U.S.C. § 103 as being unpatentable over Wokalek

6. Finally, claims 5, 14 and 19 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

We have carefully considered the issues raised in this appeal together with the examiner's remarks and appellants'

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arguments. As a result, we conclude that the rejections of the appealed claims cannot be sustained.

Considering first the § 102(b) rejection based on Cartmell, it is well settled that for a reference to be properly anticipatory, each and every element of the rejected claim must be found either expressly described or under the principles of inherency in the applied reference. *See, inter alia, RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir.), *cert. dismissed*, 468 U.S. 1228 (1984). It follows that the absence from the reference of any element of a claim negates anticipation of that claim by the applied reference. *See Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1034 (1987).

In the present case, independent claims 1, 10 and 19 are limited to a hydrogel which is partially dehydrated by removal of water. These independent claims also provide that the partially dehydrated hydrogel is impregnated into the absorbent layer such that the hydrogel can absorb wound exudate "upon contact with the said wound."

According to the examiner's position as set forth on page 4 of the answer, the hydrogel impregnated in Cartmell's absorbent

layer 18 may have a water content which is less than the preferred amount of 61% (see column 3, lines 30-35 of the Cartmell specification) and as low as 44% based on a set of weights of constituents selected by the examiner in the weight ranges disclosed in column 6, lines 30-37, of the Cartmell specification. Based on this analysis, the examiner considers the hydrogel with the smaller content of water to be partially dehydrated.

The problem with the examiner's position as outlined *supra* is that the smaller water content calculated by the examiner for Cartmell's composition is not obtained by dehydration, i.e., by removal of water. As noted in our reversal of the examiner's rejection based on this same reference in appellants' parent application (see note 2, *supra*), there is no disclosure in Cartmell, either express or inherent, that the hydrogel in the absorbent layer has been dehydrated to any extent by removal of water.

In his answer (see page 4), the examiner seems to suggest as an alternative position that the expression "partially dehydrated" is a process limitation. While the patentability of product-by-process claims as a general rule rests on the product and not on the process by which it was formed (see *In re Thorpe*,

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777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985)), it is well established patent law that process limitations in product-by-process claims must be given the same consideration as traditional product characteristics to the extent that they physically or structurally distinguish the product over the prior art (see *In re Hallman*, 655 F.2d 212, 215, 210 USPQ 609, 611 (CCPA 1981)).

In the present case, it is expected that the removal of water to partially dehydrate appellants' hydrogel will leave void spaces once occupied by the water prior to evaporation. There is no evidence before us to establish that Cartmell's undehydrated hydrogel has any corresponding void spaces. Furthermore, the Perrault patent recognizes that dehydration causes a change in the pH value of hydrogels. As a result, the physical characteristics of appellants' partially dehydrated hydrogel differ from Cartmell's undehydrated hydrogel. The examiner has not made any finding to the contrary. Therefore, even if it is assumed *arguendo* that the expression "partially dehydrated" is a process limitation, it nevertheless must be given weight in determining the patentability of the claimed subject matter over Cartmell. *Id.*

Furthermore, the hydrogel impregnated in Cartmell's absorbent layer 18 will not absorb wound exudate *upon contact with a wound* because of the presence of Cartmell's additional hydrogel layer 22 which lies between the impregnated absorbent layer 18 and the wound site. Thus, claims 1, 10 and 19 further distinguish over Cartmell by reciting that the hydrogel impregnated in the absorbent layer absorbs wound exudate upon contact with the wound.

For the foregoing reasons, we cannot agree that Cartmell is a proper anticipatory reference for the subject matter of claims 1 through 5, 7 through 14, 16, 17 and 19. We must therefore reverse the § 102(b) rejection of these claims based on the Cartmell patent.

We also must reverse the § 103 rejection of claims 1 through 5, 7 through 14, 16, 17 and 19 based on the combined teachings of Cartmell and Perrault inasmuch as Perrault does not rectify the foregoing deficiencies of Cartmell. The Perrault reference discloses a visual indicator for detecting a state of dehydration of a hydrogel composition.

Thus, while Perrault may contemplate the unintentional tendency of hydrogel to dehydrate under certain conditions during storage, it is clear from the Perrault disclosure that the

dehydration is undesirable because of the change in physical properties such as electrical conductivity of the hydrogel as discussed, for example in column 1, lines 41-44, of the Perrault specification. In view of this teaching, we cannot agree that, absent appellants' own disclosure, one of ordinary skill in the art would have been led to intentionally remove water from Cartmell's hydrogel to create a state of dehydration, which Perrault regards as undesirable. Furthermore, the Perrault patent does not state that dehydration necessarily occurs. Instead, this reference merely states that there is a tendency to dehydrate. Dehydration, therefore, is not necessarily inherent.

In any case, Perrault contains no teaching of a wound dressing in which a hydrogel impregnated in an absorbent layer of the dressing absorbs wound exudate upon contact with the wound. Thus, even if it were assumed arguendo that Perrault suggests a partial dehydration of the hydrogel in Cartmell's absorbent layer 18, the combined teachings of the two references still would not meet all of the terms of independent claims 1, 10 and 19.

Furthermore, the Robins patent, which was relied on by the examiner for an adhesive coated backing in the rejection of claim 18, does not rectify the foregoing deficiencies of Cartmell and Perrault. The combined teachings of these three references therefore would not have suggested the subject matter of claim

18. Accordingly, we must also reverse the § 103 rejection of claim 18.

With regard to the §§ 102(b) and 103 rejections based on the Wokalek patent, this reference discloses a hydrogel sheet for covering a wound site. As described in column 3, lines 20-21 of the Wokalek specification, a gauze dressing may be used to cover the hydrogel sheet, and a compression bandage may be placed on top of the gauze dressing. Based on this disclosure, the examiner has taken the position that "the gauze layer would inherently impregnate [sic, be impregnated with] the hydrogel since the hydrogel is pliable enough to adapt to the shape of the wound and it is compressed against the gauze layer also" (answer, page 5).

Even if it is assumed *arguendo* that a portion of Wokalek's hydrogel sheet will to some extent necessarily and, hence, inherently become impregnated in the overlying gauze dressing upon application of the compression bandage, the Wokalek reference is still subject to the same deficiencies discussed *supra* with regard to the Cartmell patent.

In particular, the Wokalek patent contains no disclosure, either express or inherent, that a selected water content in the disclosed range of 95% to 98% is obtained by dehydration, i.e., by removal of water. Wokalek therefore does not meet the claim

limitation that the hydrogel is partially dehydrated by removal of water. Furthermore, any hydrogel which may become impregnated in Wokalek's gauze dressing will not absorb wound exudate upon contact with the wound unless the entire sheet of hydrogel somehow becomes impregnated in the overlying gauze dressing before contact with the wound site. There is, however, no express or inherent disclosure in Wokalek that this will necessarily occur. Wokalek therefore does not meet the limitation in claims 1 and 10 that the partially dehydrated hydrogel is impregnated in the absorbent layer such that the hydrogel absorbs wound exudate upon contact with the wound.

For the foregoing reasons, we cannot agree that Wokalek is a proper anticipatory reference for the subject matter of claims 1 through 6 and 10 through 15. We must therefore reverse the § 102(b) rejection of these claims based on the Wokalek patent.

We also must reverse the § 103 of claims 1 through 6 and 10 through 15 based on the Wokalek patent. Even assuming arguendo that it would have been obvious to impregnate Wokalek's gauze dressing with hydrogel as suggested by the examiner on page 9 of the answer, we find nothing in the prior art to suggest the partial dehydration of the hydrogel by removal of water or the impregnation of the partially dehydrated hydrogel such that the hydrogel absorbs wound exudate upon contact with the wound.

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With regard to the rejection under § 112, second paragraph, the examiner contends that the Markush groups recited in claims 5, 14 and 19 render the claims indefinite because the materials set forth in each group do not belong to a recognized physical or chemical class or to an art-recognized class. Even if this is assumed *arguendo* to be the case, the claims are not necessarily indefinite. See Manual of Patent Examining Procedure (4th ed., Rev. 2, July 1996), § 2173.05(h).

In the final analysis, claims are considered to be definite as required by the second paragraph of § 112 when they define the metes and bounds of the claimed invention with a reasonable degree of precision. *In re Venezia*, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976). In the present case, the materials in each Markush group are defined with a reasonable degree of precision and are sufficiently related to make the claim language understandable. We will therefore reverse the rejection of claims 5, 14 and 19 under the second paragraph of § 112.

The examiner's decision rejecting appealed claims 1 through 19 is reversed.

REVERSED

HARRISON E. McCANDLISH)
Administrative Patent Judge)
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LAWRENCE J. STAAB)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
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APPENDIX

1. A wound dressing comprising:

a flexible absorbent layer capable of being secured to a wound on a patient; and

a partially dehydrated hydrogel material comprising a hydrogel material in which at least a portion of the water has been removed therefrom, said partially dehydrated hydrogel impregnated in said absorbent layer and supported thereby such that there are no additional support layers for said hydrogel such that said hydrogel material can absorb wound exudate upon contact with said wound.